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In The  
**United States Court Of Appeals  
For The Fourth Circuit**

**CATHERINE ANTUNES,**

*Plaintiff – Appellant,*

v.

**XAVIER BECERRA, in his official capacity as Secretary of  
U.S. Department of Health and Human Services;  
RECTOR AND VISITORS OF THE  
UNIVERSITY OF VIRGINIA,**

*Defendants – Appellees,*

and

**UNIVERSITY OF VIRGINIA HEALTH SYSTEMS; U.S. DEPARTMENT OF HEALTH AND HUMAN  
SERVICES; FOOD AND DRUG ADMINISTRATION; ROBERT CALIFF, M.D.,  
in his official capacity as Commissioner of the U.S. Food and Drug Administration,  
Defendants.**

**ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF VIRGINIA AT CHARLOTTESVILLE**

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**BRIEF OF APPELLANT**

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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No. 22-2190

Caption: CATHERINE ANTUNES v. XAVIER BECERRA, in his official capacity as

Pursuant to FRAP 26.1 and Local Rule 26.1,

Catherine Antunes

(name of party/amicus)

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who is Appellant, makes the following disclosure:  
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity?  YES  NO
2. Does party/amicus have any parent corporations?  YES  NO  
If yes, identify all parent corporations, including all generations of parent corporations:
3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity?  YES  NO  
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation?  YES  NO  
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question)  YES  NO  
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding?  YES  NO  
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim?  YES  NO  
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: 

Date: 12/02/2022

Counsel for: Appellant

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**Other Authorities:**

Brown, et. al., <i>Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021</i> , Center for Disease Control and Prevention Morbidity and Mortality Weekly Report, (August 6, 2021), at <a href="https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w">https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w</a> .....	19
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Prerak, et. al., <i>Hospitalisation among vaccine breakthrough COVID-19 infections</i> , The Lancet, (September 7, 2021), at <a href="https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00558-2/fulltext">https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00558-2/fulltext</a> .....	19
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## STATEMENT OF JURISDICTION

Plaintiff-Appellant asserted that the District Court level has jurisdiction over this case pursuant to the Administrative Procedure Act, 5 U.S.C. § 702, 28 U.S.C. §§ 1331, 1343(a)(3)-(4), and 42 U.S.C. §§ 1983 and 1988, as well as under nonstatutory equitable jurisdiction. (Third Amended Complaint, Appendix at JA10-11).

The District Court has jurisdiction under 5 U.S.C. § 702, the Administrative Procedure Act, because Plaintiff-Appellant is a person suffering a legal wrong, who has been aggrieved by an agency action, and who is seeking a judgement against the United States: specifically she is seeking declaratory and injunctive relief against the U.S. Department of Health and Human Services, the Food and Drug Administration, and its officers.

Under 28 U.S.C. §§ 1331, the District Court has jurisdiction because the claims here arise under the Constitution and statutes of the United States—specifically, Plaintiff-Appellant alleges that the defendants violated the Fourth and Fourteenth Amendments to the Constitution (all Defendants) and of the United States and the Food, Drug, and Cosmetics Act (Federal Defendants). The District Court furthermore has jurisdiction pursuant to 28 U.S.C. § 1343(a)(3)-(4), because the Plaintiff-Appellant seeks prospective redress against UVA, a state actor, in its official capacity to end the deprivation, under state law, of her rights, privileges, and immunities secured by federal law.

42 U.S.C. §§ 1983 and 1988 confer jurisdiction upon the District Court because UVA was acting under color of the statutes, customs, and usages of the Commonwealth of Virginia to deprive Plaintiff-Appellant of her rights, and she brought this action for the protection of her civil rights and for their vindication.

The District Court also has jurisdiction under its equitable powers permitting it to issue nonstatutory injunctions to protect the Plaintiff-Appellant against state actors, in this case all defendants. See *Trump v. Vance*, 140 S. Ct. 2412, 2428-29 (2020) [citing *Ex parte Young*, 209 U.S. 123, 155–156 (1908) (holding that federal courts may enjoin state officials to conform their conduct to federal law)]. Here Plaintiff-Appellant requests that a federal court enjoins a state actor, UVA, from persisting in the actions that caused her separation, and restoring her to employment. This Court has found that, “[p]ursuant to *Ex parte Young*, the Eleventh Amendment does not bar a citizen from suing a state officer to enjoin the enforcement of an unconstitutional law when the officer has ‘some connection with the enforcement of the act.’” *Bostic v. Schaefer*, 760 F.3d 352, 371 n.3 (4th Cir. 2014)(quoting *Lytle v. Griffith*, 240 F.3d 404, 412 (4th Cir. 2001)(emphasis omitted) (Virginia’s Registrar of Vital Records could be sued under *Ex parte Young* for unconstitutional actions related to marriage rights because he was charged with ensuring compliance with the Commonwealth’s marriage laws)). Defendants UVA possess the necessary connection to the establishment and enforcement of UVA Health’s vaccine mandate for the District Court to invoke its injunctive power.

This Court has appellate jurisdiction under 28 U.S.C. § 1291. The District Court issued a final order granting Defendants' motions to dismiss on September 12, 2022 and disposing of all of Plaintiff-Appellant's claims. She filed a timely appeal on November 14, 2022, pursuant to Fed. R. Civ. P. 4(a)(1)(B)(ii)-(iii).<sup>1</sup>

## **STATEMENT OF THE ISSUES**

- I. Whether Plaintiff-Appellant's claims against Federal Defendants should have been dismissed pursuant to FRCP 12(b)(1) because lack of subject matter jurisdiction:
  - a. Whether Plaintiff-Appellant's termination of employment is fairly traceable to Federal Defendants thus conferring standing to sue Federal Defendants for violations of the Food, Drug, and Cosmetics Act and the 14<sup>th</sup> Amendment of the U.S. Constitution.
  - b. Whether the federal government's waiver of sovereign immunity in the Administrative Procedure Act is applicable in this case, where Plaintiff-Appellant seeks to sue Federal Defendants for failure to apply provisions of Food, Drug, and Cosmetics Act and the 14<sup>th</sup> Amendment of the U.S. Constitution.
- II. Whether Plaintiff-Appellant's claims against UVA should have been dismissed pursuant to FRCP 12(b)(6) because of a failure to state a claim:

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<sup>1</sup> Sixty days from the September 12, 2022, Order is November 11, 2022, which was Veteran's day, a Federal holiday. Per Fed. R. Civ. P. 26(a)(2)(C), the deadline extends to the next business day, November 14, 2022.

- a. Whether the Plaintiff-Appellant has alleged facts supporting the allegation that UVA violated the Due Process Clause of the 14<sup>th</sup> Amendment with regard to unwanted medical treatment, and whether Plaintiff-Appellant has identified a right triggering heightened protection under substantive due process or demonstrated any arbitrary, egregious, and conscience-shocking governmental action. Whether the District Court applied rational basis standard properly in this case.
- b. Whether Plaintiff-Appellant has alleged facts supporting the allegation that UVA violated the Fourth Amendment, and if the if it is a seizure whether it is a reasonable one, and whether it is Plaintiff-Appellant who must demonstrate that it is or is not.
- c. Whether Plaintiff-Appellant has alleged facts supporting the allegation that UVA's vaccination requirement amounts to an unconstitutional condition, including whether the doctrine applies in the context of at-will employment for a state entity.

## **STATEMENT OF THE CASE**

On November 9, 2021, the Rector and Board of Visitors of the University of Virginia ("UVA") fired Ms. Catherine Antunes<sup>2</sup>, an experienced Registered Nurse in good standing who had been with them from January, 2020 until then. Ms. Antunes

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<sup>2</sup> Pronounced ANN-toons

had worked overtime with UVA throughout the COVID-19 pandemic and had displayed “astute clinical skills” and “natural leadership ability.”

UVA fired Ms. Antunes according to its Health System’s policy, announced in August of 2021, which stated that, on pain of termination, all health personnel must be vaccinated using one of the available COVID-19 vaccinations, all of which the Food and Drug Administration (FDA) / Department of Health and Human Services (HHS) and its principals, the Commissioner of the FDA and the Secretary of HHS (together the “Federal Defendants”) approved according to the Emergency Use provision of the Food, Drug, and Cosmetics Act (FDCA). (Third Amended Complaint, Appendix at JA47-48; JA29-34). UVA opined soon after announcing its mandate that is “unclear” if the mandatory vaccination policy was legal. As to the question of whether it was ethical, according to UVA, it “depends on who you ask.” (*See*, Third Amended Complaint, Appendix at JA52).

HHS for its part had no policy in place to discourage and / or prevent UVA’s vaccination policy or Ms. Antunes’s termination, or to impose any consequences upon UVA for terminating an employee who refused a treatment authorized under the FDCA’s Emergency Use provisions. This is despite language within the FDCA which states that the HHS Secretary must provide “appropriate conditions designed to ensure that individuals to whom the product is administered are informed of the option to accept or refuse administration of the product, of the consequences, if any,

of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.” 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

Meanwhile, clinical trials were ongoing for all of the available vaccines, and per HHS regulation, the participants in these trials, who were receiving identical formulations of the vaccine, were the beneficiaries of explicit HHS regulatory protections against coercive pressure to accept them. (Third Amended Complaint, Appendix at JA20-22).

Ms. Antunes originally filed for a Temporary Restraining Order on November 9, 2021, to prevent her termination, which the District Court denied. UVA terminated her on the same day. She amended her complaint to pray for declaratory and injunctive relief that would restore her to her employment at UVA and would provide her compensation for the financial difficulty she had suffered. Both UVA and the Federal Defendants moved to dismiss her complaint according to F. R. Civ. P. 12(b)(1) and 12(b)(6). The District Court held oral arguments on the Motions to Dismiss on August 26, 2022 and issued a Final Order granting the motions to dismiss on September 12, 2022. (Final Order, Appendix at JA77). Ms. Antunes filed her Notice of Appeal on November 14, 2022. (Appendix at JA78-79).

## **SUMMARY OF ARGUMENT**

Ms. Antunes’s termination was unlawful because UVA conditioned her employment on her acceptance of a medical treatment that she did not want, and the Federal Defendants had an obligation to prevent such a termination. This civil right to

be free of unwanted bodily touching and intrusion—and coercive pressure to accept it—is rooted in the following provisions of the U.S. Constitution and the laws of the United States:

- The plain language of the U.S. Constitution forbade her termination when the Fourth Amendment stated that “[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated[.]”
- The Fourteenth Amendment of the U.S. Constitution guarantees the equal protection of the laws, but the Federal Defendants afforded more protections to one class of vaccine recipients than another similarly situated class of vaccine recipients.
- The U.S. Supreme Court has stated that “[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.” *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278 (1990).
- The Supreme Court has also prohibited states from imposing unconstitutional conditions on employment. See, e.g., *Federal Communications Commission v. League of Women Voters of California et al.*, 468 U.S. 364 (1984).
- Ms. Antunes’s termination is also unlawful because the Food, Drug, and Cosmetics Act states that the HHS Secretary was bound to create “appropriate

conditions designed to ensure that individuals to whom the product is administered are informed of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.” 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

These assertions on behalf of Ms. Antunes deserve to have a full hearing in Court, and the District Court’s dismissal of them is an error, particularly in light of this Court’s exhortation that, when “a Rule 12(b)(6) motion is testing the sufficiency of a civil rights complaint, we must be especially solicitous of the wrongs alleged and must not dismiss the complaint unless it appears to a certainty that the plaintiff would not be entitled to relief under any legal theory which might plausibly be suggested by the facts alleged.” *Harrison v. United States Postal Serv.*, 840 F.2d 1149, 1152 (4th Cir. 1988)(internal citations omitted).

The District Court also erred when it found that Ms. Antunes lacks standing with respect to the Federal Defendants. Mr. Antunes’s termination is traceable to HHS because the FDCA directly required HHS to have some mechanism in place to prevent Ms. Antunes’s termination prevent the administration of the vaccines in question in coercive circumstances.

The District Court erred further when it ruled that HHS’ lack of action in this circumstance was not reviewable under the Administrative Procedure Act, which provides a “limited waiver of sovereign immunity” applicable here. The Court erred

by finding that the Federal Defendants' actions were committed to agency discretion. While some actions are committed to agency discretion under the FDCA, the lack of action Ms. Antunes identifies in her complaint is not.

## INTRODUCTION

While the facts of this case implicate a variety of legal theories, it boils down to a single question. Is it acceptable to harass and coerce someone to obtain consent to do something that would constitute a legal offense without that consent?

In the realm of sexual harassment, this is easy—harassment is as illegal as overt sex discrimination. But in the context of an employer mandate over a vaccine, it seems that some courts, including the District Court here, want to come up with a different answer. The problem is that they do not provide any legal or intellectual framework for why the one type of coercive pressure is okay, but the other is not. We are left with some form of the idea that, according to precedent regarding vaccines, this is the way things have been. While there are certainly differences between medical treatment and sexual relations, there are some similarities that leave much of the current discussion over this issue that has occurred in the courts, including the District Court here, wanting.

It is against this backdrop that this Court should note the prominence of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) in decisions regarding COVID-19 vaccines, including in the District Court below. In terms of legal developments, *Jacobson* is ancient history. If it stands for the proposition that UVA may harass Ms. Antunes

until she either quits her job or accepts an injection she does not want, it comes from an era in which she could not vote, in which UVA could refuse to hire her because she is a woman without legal consequence, and in which the law did not do much if anything to prevent her supervisor from exerting the same coercion to accept his sexual advances.

An additional reality is that *Jacobson* is not well relied-upon precedent. It made its appearance in *Zucht v. King*, 260 U.S. 174 (1922) on its way to providing the justification for the unconscionable results in *Buck v. Bell*, 274 U.S. 200 (1927).<sup>3</sup>

Since 1922 American culture, including the law, has tried to move beyond this notion of forced medical treatment and experimentation, particularly after witnessing and fighting against the horrors of Nazi medical regime, and being rocked internally by the Tuskegee experiments.<sup>4</sup>

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<sup>3</sup> It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. Three generations of imbeciles are enough. *Buck*, 274 U.S. 207 (1927).

<sup>4</sup> Jean Heller, *Syphilis Victims in U.S. Study Went Untreated for 40 Years*, THE NEW YORK TIMES, (July 26, 1972), available at <https://www.nytimes.com/1972/07/26/archives/syphilis-victims-in-us-study-went-untreated-for-40-years-syphilis.html>. (Dr. J.D. Millar, head of the Venereal Disease branch of the Center for Disease Control stated at the time: “[T]he study began when attitudes were much different on treatment and experimentation. At this point in time, with our current knowledge of treatment and the disease and the revolutionary change in approach to human experimentation, I don’t believe the program would be undertaken.”)

It did so by developing a robust culture of informed consent.<sup>5</sup> While it is possible to offer an exhaustive historical treatment of these developments, mentioned in some detail in the footnotes, it is enough to note that Courts are not citing precedent from another era—something post Jim Crow, for example.

The issues involved in the question of mandatory COVID-19 vaccination regimes, including the statutory framework surrounding them, are more fraught than the Courts to date seem to acknowledge. This seems to be what we have in the District Court opinion below. Ms. Antunes encourages this Court to take a different approach.

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<sup>5</sup> See, e.g., HHS.gov, The Belmont Report, at <https://www.hhs.gov/ohrp/regulations-and-policy/belmontreport/index.html>:

Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance...Unjustifiable pressures usually occur when persons of authority or commanding influence--especially where possible sanctions are involved-- urge a course of action for a subject. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

*See also*, The American Medical Association Code of Medical Ethics Opinion 2.1.1: Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. (available at: <https://www.ama-assn.org/deliveringcare/ethics/informedconsent#:~:text=Code%20of%20Medical%20Ethics%20Opinion%202.1.1&text=Patients%20have%20the%20right%20to,ands%20supports%20shared%20decision%20making.>)(Last visited January 23, 2023).

## ARGUMENT

### I. Standard of Review

When reviewing a motion to dismiss on appeal under Federal Rule of Civil Procedure 12(b)(1), this Court will “review the district court's factual findings with respect to jurisdiction for clear error and the legal conclusion that flows therefrom *de novo*.” *In re KBR, Inc., Burn Pit Litig.*, 744 F.3d 326, 333 (4th Cir. 2014)(citation and internal quotations omitted).

With respect to a Rule 12(b)(6) dismissal, this Court reviews under the *de novo* standard, evaluating “whether the complaint states a claim to relief that is plausible on its face.” *United States ex rel. Oberg v. Pennsylvania Higher Educ. Assistance Agency*, 745 F.3d 131, 136 (4th Cir. 2014) (citations and internal quotations omitted).

### II. The Fourth and the Fourteenth Amendment of the U.S. Constitution prevent UVA from imposing a vaccine requirement on Ms. Antunes

#### a. Legal standard: 12(b)(1) and 12(b)(6) motions to dismiss

The District Court dismissed Ms. Antunes's claims against UVA pursuant to its Rule 12(b)(6) motion to dismiss.

Fed. R. Civ. P. 12(b)(6) “is to test the sufficiency of a complaint.” *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). The Rule “does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses,” *Id*, citing *Republican Party v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). A Rule 12(b)(6)

motion should only be granted if, “after accepting all well-pleaded allegations in the plaintiff’s complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff’s favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief.” *Id.*

There is an additional consideration when, as here, a Rule 12(b)(6) motion is testing the sufficiency of a civil rights complaint, in that the reviewing Court “must be especially solicitous of the wrongs alleged and must not dismiss the complaint unless it appears to a certainty that the plaintiff would not be entitled to relief under any legal theory which might plausibly be suggested by the facts alleged.” *Id.*, citing *Harrison v. United States Postal Serv.*, 840 F.2d 1149, 1152 (4th Cir. 1988).

The District Court did not meet this standard in this case.

**b. Coercive pressure to accept unwanted medical treatment should be barred by the same principles that bar the administration of unwanted medical treatment**

Virginia has a very strong legal tradition recognizing the importance of informed consent in medical treatment. Absent that consent, Virginia courts recognize that a medical professional is guilty of battery or trespass:

Under Virginia law [...] the tort of battery is “an unwanted touching which is neither consented to, excused, nor justified.” *Koffman v. Garnett*, 265 Va. 12, 574 S.E.2d 258, 261 (Va. 2003). The Supreme Court of Virginia has recognized that the relationship between a physician and a patient is a consensual one. *Washburn v. Klara*, 263 Va. 586, 561 S.E.2d 682, 685 (Va. 2002). Thus, “unless an emergency or unanticipated problem arises, a physician or surgeon must first obtain the consent of a patient before treating or operating on that patient.” *Id.* In the absence of an unanticipated problem or emergency, a medical procedure or operation

performed without a patient's consent constitutes a "technical" battery. *Id.* (internal citations and quotations omitted); see also *Pugsley v. Privette*, 220 Va. 892, 263 S.E.2d 69, 74 (Va. 1980) ("A surgical operation on the body of a person is a technical battery or trespass unless he or some authorized person consented to it.") (internal citations, quotations, and alterations omitted). A technical battery also occurs when a medical procedure is performed that exceeds the scope of a patient's consent, or a medical procedure is continued after a patient's consent has been unequivocally withdrawn. See *Washburn*, 561 S.E.2d at 686 (battery claim predicated on the allegation that the defendant exceeded the scope of the plaintiff's consent by performing a diskectomy at the C7-T 1 level of the plaintiff's spine, even though she only consented to a diskectomy at the C6-7 level); *Woodbury v. Courtney*, 239 Va. 651, 391 S.E.2d 293, 294, 6 Va. Law Rep. 2226 (Va. 1990) (battery claim predicated on the assertion that the defendant exceeded the scope of the plaintiff's consent to a breast biopsy by ultimately performing a partial mastectomy); *Pugsley v. Privette*, 263 S.E.2d at 74-76 (battery claim predicated on the assertion that the plaintiff withdrew her consent prior to surgery, and thus, that she was operated on by a surgeon without her consent). *Morillo v. Shenandoah Mem'l Hosp.*, 547 F. Supp. 2d 528, 531 (W.D. Va. 2008)

Here the question arises whether coercive pressure to accept a medical procedure can be an offense as well.

Appellant asserts that it can, and this Court should recognize that principle here. There was a time when "the American legal system offered women scant protection from sexual coercion at work [...] most free women sexually coerced at work would have little reason to expect the state to sanction the men who took advantage of them." Reva B. Siegel, *A Short History of Sexual Harassment*, in DIRECTIONS IN SEXUAL HARASSMENT LAW 4, (Catherine McKinnon, ed. 2003). Sexual harassment was a feature baked into chattel slavery, domestic servitude, and industrial age factory work. New York's high court in 1874, to take only one example,

rejected a rape conviction of a man who assaulted his fourteen-year-old servant girl, after locking her younger siblings in his barn. *Id.*

Decades of legal and social advances, including women's suffrage, gradually began to change this balance, but it was gradual. "At first, courts simply refused to acknowledge that sexual harassment had anything to do with employment discrimination on the basis of sex. Sexual harassment was rejected as a personal matter having nothing to do with work or a sexual assault that just happened to occur at work." *Id* at 11.

Eventually, however, this view began to change.<sup>6</sup> In 1977, the *Barnes v. Costle* case solidified the legal convention that has stood for over 40 years and has led to the protection of countless women (and men)—that sexual harassment is discrimination on the basis of sex and carries with it legal consequences. 561 F.2d 983 (D.C. Cir. 1977).

In 1977, it took a Court to make the connection between harassing conduct and behavior that existing text and legal conventions already recognized as unlawful. The question here for this Court is whether precedent prohibiting harassment in the context of sex discrimination translates into the context of harassment in the pursuit of unwanted medical battery. Ms. Antunes submits that it does.

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<sup>6</sup> *Munford v. James T. Barnes & Co.*, 441 F. Supp. 459 (E.D. Mich. 1977) provides a contemporary survey of cases that illustrate well this gradual acceptance that sexual coercion in the work context constitutes discrimination on the basis of sex.

Where it is battery, harassment in pursuit of it is, or ought to be, battery. Where it is a violation of the Fourth Amendment, harassment in pursuit of it is, or ought to be, a violation of the Fourth Amendment. Where it is a violation of the Fourteenth Amendment, harassment in pursuit of it is, or ought to be, a violation of the Fourteenth Amendment.

**c. The Fourth Amendment of the U.S. Constitution bars UVA's mandate**

The Fourth Amendment of the U.S. Constitution states in relevant part that, “The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated[...].”

Ms. Antunes puts this forth as the most natural place in the U.S. Constitution to locate the principal that a person has a liberty interest in remaining free from unwanted medical interventions as, unlike the Fourteenth Amendment, it has the words right in it: “The right of the people...to be secure in their persons...shall not be violated.”

The District Court described this approach as “novel” and notes that Ms. Antunes cited no authority for taking such an approach in this context. (Memorandum Opinion, Appendix at JA71.) Ms. Antunes acknowledges the novelty of this approach (this would explain the lack of authority available), but although it is somewhat of a departure from both “bodily integrity” type jurisprudence and Fourth Amendment jurisprudence, Ms. Antunes offers it here as a return to its roots—the text of the Constitution.

To the extent that such an approach would fit squarely within existing Fourth Amendment jurisprudence, as the District Court acknowledged, a Fourth Amendment seizure occurs when there is a “a show of authority” that “in some way restrain[s] the liberty of” a person. *Terry v. Ohio*, 392 U.S. 1, 19, n.16 (1968).

Here we certainly have a show of authority—UVA employed Ms. Antunes, threatened her employment, and then fired her. The threats and ultimate termination Ms. Antunes experienced restrained her liberty to decline unwanted medical treatment by exerting coercive pressure on it. *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, (1990).

The District Court notes that Ms. Antunes never received a vaccination. (Memorandum Opinion, Appendix at JA72). While this is true, this brings us back to the question of whether coercion in pursuit of such an offense is excusable, and we would urge the Court to find that it is not.

This turns us to the question of reasonableness, as the Fourth Amendment offers protection only against searches and seizures that are unreasonable. *e.g., Florida v. Jimeno*, 500 U.S. 248, 250 (1991). The District Court ruled that “Plaintiff has alleged no facts, taken as true, that would establish that the vaccination policy intrudes on her Fourth Amendment interests in a manner outweighing UVA Health’s promotion of legitimate governmental interests.” (Memorandum Opinion, Appendix at JA73).

This assumes as true the very thing that Ms. Antunes seeks to dispute in a full hearing. Even supposing that the health of patients and employees at UVA is the

legitimate government interest that it seeks to promote in this context, it is not enough simple to intone some formulation of the words “public health considerations.” The question is whether the vaccination policy in question actually promotes that interest as a factual matter.

The case for that idea was never very strong. There seems, for example, to be no way to square the idea that vaccinations are necessary for the health of the environment and any delay in the implementation of a mandate. The explanation could be that practical considerations outweighed health considerations for a time, but that only leads to the question of why Ms. Antunes’s liberty interests could not also outweigh this public health justification.

Furthermore, there seems to be no way to square, from a public health perspective, any religious or medical accommodation that UVA might have offered and the idea that Ms. Antunes could not also stay on as an employee.

As for the vaccine itself, we know from solid scientific evidence that:

- People who have had the vaccine can still become sick with COVID-19.<sup>7</sup>
- People who have had the vaccine can still spread the disease.<sup>8</sup>

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<sup>7</sup> Prerak, et. al., *Hospitalisation among vaccine breakthrough COVID-19 infections*, THE LANCET, (September 7, 2021), at [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00558-2/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00558-2/fulltext).

<sup>8</sup> Brown, et. al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021*, CENTER FOR DISEASE CONTROL AND PREVENTION

- People who have had the vaccine can still spread the disease to other people who have had the vaccine.<sup>9</sup>
- Personal Protective Equipment (PPE) prevents the spread of COVID-19.<sup>10</sup>

It seems difficult, and Ms. Antunes asserts here that it is impossible, to maintain a public health justification at trial in light of these considerations. But in the context of a motion to dismiss, this is the point—these issues necessitate and deserve a full ventilation at the trial phase.

**d. The Fourteenth Amendment of the U.S. Constitution bars UVA's vaccine mandate**

In her complaint, Ms. Antunes asserted that UVA's vaccine mandate constituted an offense against her protected liberty interest in refusing medical treatment. “[T]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.” *Cruzan ex rel. Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278 (1990).

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MORBIDITY AND MORTALITY WEEKLY REPORT, (August 6, 2021), at [https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s\\_cid=mm7031e2\\_w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w)

<sup>9</sup> *Id.*

<sup>10</sup> Sohil R. Sud, MD, MA, COVID-19 and Keeping Clean: A Narrative Review To Ascertain the Efficacy of Personal Protective Equipment To Safeguard Health Care Workers Against SARS-CoV-2, 10 Hosp. Pediatrics 570, 573 (July 2020), at <https://hosppeds.aappublications.org/content/hosppeds/10/7/570.full.pdf>.

The District Court was dismissive of these claims, citing various courts throughout the country—none of them controlling, and all of them in one way or another sending us back to 1905 and *Jacobson*, which is where the District Court wanted to take us as well. (Memorandum Opinion, Appendix at JA69-70).

In the first place, *Jacobson* is factually distinguishable from the circumstances at hand. *Jacobson* arose in the context of a smallpox pandemic, “which was of a different nature than the COVID-19 pandemic of the last few years. For example, [...] the smallpox fatality rate among the unvaccinated was about 26 percent; by contrast, the COVID-19 infection fatality rate was estimated in January 2021 to be somewhere between 0.0-1.63 percent.” *Lukaszczuk v. Cook Cty.*, 47 F.4th 587, 600 (7th Cir. 2022).

The mandate in question in *Jacobson* arose from a state law and an ordinance—in other words, acts of duly elected legislative bodies exercising their police powers. UVA’s does not have police powers and has not cited any statewide legislation or policy that forms the basis of its vaccination mandate. Thus, its internal personnel policy does not represent the legislative determination of Ms. Antunes’s peers in a manner that is in any way similar to a legislative body. In the latter context, she would have an official vote in the matter, as would her peers.

Also, *Jacobson* paid five dollars—about \$140 in today’s dollars—as a fine for his noncompliance, not with his livelihood as Ms. Antunes did. *See, Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020)(Gorsuch, J., concurring).

Even if the Court were to find that *Jacobson* is applicable here, Appellant urges a highly considerate approach, one that considers fully the continued wisdom of reliance on *Jacobson* to the extent that Courts of late have seemed inclined to rely on it. At least one Supreme Court Justice has warned against assigning to that “modest decision” the “towering authority” that “overshadows the Constitution during a pandemic.” *Id.*

The District Court, citing *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999), and *Waybright v. Frederick Cnty., Md.*, 528 F.3d 199, 205 (4th Cir. 2008) indicated that Ms. Antunes’s claims did not: (1) identify any right triggering heightened protection under substantive due process or (2) demonstrate any arbitrary, egregious, and conscience-shocking governmental action. (Memorandum Opinion, Appendix at JA70-71).

Starting with our consciences: the factual considerations about the features of UVA’s mandate indicate an arbitrariness that does not fit easily into any coherent scientific framework. We have furthermore mentioned where the reasoning in *Jacobson* leads us—to *Buck v. Bell*, a result that shocks the conscience and that the Supreme Court should address at its nearest opportunity, along with *Jacobson*, perhaps.

*Jacobson* itself seemed to encourage this approach when it stated,

Before closing this opinion we deem it appropriate, in order to prevent misapprehension as to our views, to observe...that the police power of a state, whether exercised directly by the legislature, or by a local body acting under its authority, may be exerted in such circumstances, or by

regulations so arbitrary and oppressive in particular cases, as to justify the interference of the courts to prevent wrong and oppression.  
*Jacobson v. Massachusetts*, 197 U.S. 11, 38, 25 S. Ct. 358, 366 (1905).

This leads us to the right in question. In *Cruzan*, the Supreme Court described it as a “constitutionally protected liberty interest.” *Cruzan*, 497 U.S. at 278 (1990). There is, indeed, ample relevant jurisprudence that gives the notion of bodily integrity the treatment of worthy of heightened protection under Substantive Due Process. *See generally, Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2317 (2022)(Kagan, dissenting opinion).

If we are following the logic of some courts, including the District Court, somehow vaccination represents a carve-out in this bodily integrity framework, where other considerations overtake the right of a person to refuse unwanted medical treatment.

This approach of plucking *Jacobson* back out of its 1905 context and breathing into it fresh and formidable influence over our jurisprudence assumes a lot. It assumes that nothing has happened since 1905 that would bear on how *Jacobson* translates into a jurisprudence that has since seen: the overturning of that same 1905 Court’s *Lochner v. New York* 198 U.S. 45 (1905); women gain the right to vote, admission to the bar, and elevation to the bench; *Buck v. Bell* and the eugenics movement<sup>11</sup>; the end of Jim

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<sup>11</sup> See, e.g., Teryn Bouche and Laura Rivard, *America's Hidden History: The Eugenics Movement*, Scitable by Nature Education, (September 18, 2014), available at <https://www.nature.com/scitable/forums/genetics-generation/america-s-hidden-history-the-eugenics-movement-123919444/>.

Crow era; the beginning of the Civil Rights era; the application of Title VII of the Civil Rights Act to sexual harassment; the rise of abortion rights; the fall of abortion rights; the Tuskegee experiments; the Belmont Report; the modern informed consent state; and numerous other cultural and legal developments.

Ms. Antunes urges this Court to adopt the view that *Cruzan*, in citing *Jacobson* for the proposition that one can be free from unwanted medical treatment, was not continuing its legal tradition untouched, but was instead taking it in a new direction, or perhaps that in the 30 plus years since the Court handed *Cruzan* down, that there have been additional developments that would call for a fresh approach.

**e. UVA's mandate imposed an Unconstitutional Condition on Ms. Antunes's employment**

Ms. Antunes alleged in her complaint that UVA's vaccine mandate constituted an unconstitutional condition on her employment.

The U.S. Supreme Court has recognized this principle in public employment in *Elrod v. Burns*, 427 U.S. 347 (1976), which held that a local official could not impose unconstitutional conditions on public employment, in that case, a Sheriff's office.

Numerous other cases have followed suit, including *Keyishian v. Board of Regents of University of State of New York*, 385 U.S. 589(1967)(Board of Regents of the State University of New York could not condition employment on an unconstitutional plan to prevent employment by "subversive" persons); *Pickering v. Board of Education of Township High School District 205, Will County, Illinois*, 391 U.S. 563,(1968)(Board of education could not impose unconstitutional restrictions on teacher's freedom of

speech); *Perry v. Sindermann*, 408 U.S. 593 (1972)(Court upholds appellate court determination that termination of non-tenured professor for criticism would violate the Fourteenth Amendment, if the termination was based on his protected free speech); *Branti v. Finkel*, 445 U.S. 507(1980)(Democratic public defender's termination of two Republican Assistant Public Defenders violated the First and Fourteenth Amendments).

Of special note here is *Perry v. Sinderman*, where the employee in question was non-tenured. As the court stated then,

The first question presented is whether the respondent's lack of a contractual or tenure right to re-employment, taken alone, defeats his claim that the nonrenewal of his contract violated the First and Fourteenth Amendments. We hold that it does not.

For at least a quarter-century, this Court has made clear that even though a person has no "right" to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interest[.] *Perry v. Sindermann*, 408 U.S. 593, 596-97, 92 S. Ct. 2694, 2697 (1972)

This language belies the District Court's treatment of the doctrine, which stated, citing *Waters v. Churchill*, 511 U.S. 661, 679 (1994)(plurality opinion) that "an at-will employee . . . generally has no claim based on the Constitution at all." Generally, this is true—the exception is when there is an unconstitutional condition imposed on her employment. The issue, according these cases, is not whether a person is at-will or not.

**f. UVA and Federal Defendants violated the Equal Protection clause by setting**

The Equal Protection Clause of the Fourteenth Amendment to the United States Constitution provides that “[n]o state shall deny to any person within its jurisdiction the equal protection of the laws.”

**III. The Food, Drug, and Cosmetics Act and its regulatory implementation by the Federal Defendants as viewed in light of the Equal Protection Clause, required the Federal Defendants to prevent UVA’s termination of Ms. Antunes**

**a. The Food, Drug, and Cosmetic Act requires protections against coercive measures**

The Food, Drug, and Cosmetic Act, 21 U.S. Code § 360bbb–3(e)(1)(A)(ii)(III), includes consumer protections for products approved under the Emergency Use provisions of the statute.

In particular, provision requires that the HHS Secretary “ensure that individuals to whom the product is administered are informed...of the option to accept or refuse administration of the product.” *Id.*

The plain statutory language here references “the option” without elaboration, which admittedly seems a bit out-of-place. The District Court would interpret this “option” out of the statute, as it ruled that Ms. Antunes’s claims should be dismissed under Rule 12(b)(1) for lack of traceability and redressability, reasoning that, “She does not offer any allegations that Federal Defendants participated in UVA Health’s decision to suspend or terminate her or that they have authority to direct UVA Health

to rehire Plaintiff. Nor does she allege she would seek to regain her position if claims against the Federal Defendants succeed.” (Memorandum Opinion, Appendix at JA64).

This passage misses Ms. Antunes’s argument. Her complaint seeks, through declaratory and injunctive relief, a return to the *status quo* before the unlawful acts, but with a further finding that the Federal Defendants’ lack of adherence to the text of the FDCA was unlawful and needed to change. (Third Amended Complaint, Appendix at JA23).

The presence of text in the FDCA explicitly referencing an “option” imposes, by virtue of its presence in the text, an obligation on somebody to ensure that there exists an option. The only plausible option, by virtue of the structure of the statute, is the Secretary of HHS.

In other words, the statute imposes on Federal Defendants the obligation actively to work to prevent incidents like what occurred with UVA and Ms. Antunes. How? The answer to such a question is the Administrative Branch of the government exists, but it seems as though one option would be a regulatory scheme tying important grants and funding streams (*e.g.* Medicare payments) to the existence of such protections at grantee entities. UVA will have re-hired Ms. Antunes, and the Federal Defendants would have mechanisms in place that would ensure they never fire her for not taking an EUA product. It would have a direct obligation with regard to Ms. Antunes’s employment through her employer, satisfying the traceability

requirement.

Specific regulations aside, such an approach—that the Secretary ensures an option, ideally tied to funding or access to COVID-19 vaccines—makes it ““likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision,” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561(1992) seems to be the only approach that can make any sense out of the provision.

**b. The APA’s limited waiver of sovereign immunity clearly applies in this circumstance**

Ms. Antunes’s seeks injunctive relief requiring Federal Defendants to perform a task they are legally obligated to perform. (Third Amended Complaint, Appendix at JA 24).

The Administrative Procedure Act provides:

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. 5 U.S.C. §702.

Furthermore, The Administrative Procedure Act (“APA”) provides a limited waiver of sovereign immunity but exempts “agency action [that] is committed to agency discretion by law,” from judicial review. 5 U.S.C. § 701(a)(2).

The District Court points out that, under the FDCA, 21 U.S.C.

§260bbb03(i), Congress has committed “Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.”

Here, Ms. Antunes agrees that she would not be able to challenge the Secretary’s final determination about an Emergency Use Authorization. Ms. Antunes’s challenge is not, however, about anything “under the authority” of the FDCA. Ms. Antunes’s request for review is a request for a review of whether to apply the FDCA at all. It is, in other words, within the purview of the Federal Defendants to make a determination according to the terms of the FDCA, but is not within their purview to determine that certain explicit terms of the statute do not apply to them, or that they are free to ignore them. She is not challenging how the Secretary provided the “options” mentioned in the statute; she is noting that the Secretary failed to provide the options at all.

**c. The Equal Protection clause compels Federal Defendants to extend protections it extends to trial recipients of the vaccines to users under the EUA provisions of the FDCA**

Government Defendants have afforded two separate levels of protection to two groups of people—1) participants in the ongoing clinical trials for the various COVID-19 vaccines, and 2) those who are receiving the vaccines pursuant to an EUA authorization outside of the context of the ongoing clinical trials. Both groups are receiving the same vaccines, and are in every way similarly situated, but are receiving unequal levels of protection.

21 CFR Part 50 applies to:

[A]ll clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

The regulation goes on to state that, except in situations where conditions make informed consent impossible (where, for example, there is an immediate danger and a medical condition makes consent impossible):

[N]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

These are the protections that those who are receiving the vaccines as part of a clinical trial must receive as a matter of HHS' regulatory scheme.

This is unequal treatment of two similarly situated classes of people: recipients of the vaccine under the EUA provisions on the one hand, and recipients of the vaccine through the clinical trials on the other. Those who receive the vaccine as part of the EUA authorization do not, because of the Government Defendants' failure to act, receive the statutory protections found in the EUA statute.

This sort of disparity fails any rational basis test, as there can be no justification for failing to protect one group as much as the other despite the fact that they are receiving the same formulation of the vaccine, at the same level of development, from the same manufacturers, contemporaneous with one another.

## **CONCLUSION**

The District Court erred when it granted the Motion to Dismiss in this case. Ms. Antunes clearly had standing to bring her claims, which were substantive enough to state a claim sufficient for a finding in her favor, according the Food, Drug, and Cosmetics Act and the U.S. Constitution.

## **REQUEST FOR ORAL ARGUMENT**

Appellant requests oral argument.

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Respectfully submitted,

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